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AUG 9 1996

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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,808,614, which issued February 28, 1989, was filed on July 12, 1996, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, GEMZAR®, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent may not be eligible for extension of the patent term under 35 U.S.C. § 156 since the subject patent does not claim the active ingredient gemcitabine hydrochloride, which is a salt, or an ester of the active ingredient.[1]

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[1]While the language of 35 U.S.C. § 156 (a) allows patents which "claims a product" to receive an extension with specified rights, the "product" which must be claimed is "a new drug ... including any salt or ester of the active ingredient" (35 USC § 156(f)(2)) which has been subject to a regulatory review period before its first commercial marketing or use (35 U.S.C. § 156(a)(4)). See Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (CAFC 1990)(prior approval of a salt of cefuroxime did not prevent a later approval of cefuroxime acetil (an ester of cefuroxime) from being considered the first permitted commercial marketing or use of the active ingredient cefuroxime acetil, even when the definition of "product" of 35 U.S.C. § 156(f)(2) was considered).